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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,185	09/07/2001	Franz-Josef Meyer-Almes	P66688US0	6405

136 7590 09/26/2003

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[REDACTED] EXAMINER

SAUCIER, SANDRA E

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 09/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/856,185	MEYER-ALMES, FRANZ-JOSEF
	Examiner Sandra Saucier	Art Unit 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
 - 2a) This action is FINAL. 2b) This action is non-final.
 - 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- Disposition of Claims**
- 4) Claim(s) 15-28 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 - 5) Claim(s) _____ is/are allowed.
 - 6) Claim(s) 15-28 is/are rejected.
 - 7) Claim(s) _____ is/are objected to.
 - 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 07 September 2001 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 10/01/01 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because it lacks the journal name, volume and issue of the journal in the citation on PTO 1449. Thus, the citations are incomplete. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on 3/12/1999. It is noted, however, that applicant has not filed a certified copy of the foreign application as required by 35 U.S.C. 119(b).

Claim Rejections – 35 USC § 112

Claims 16–28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Claims 15, 16, 18, 22, 23, 24, 25 not have any active steps. Method claims should be in the active voice, "incubating", "detecting", "adding" "performing".

Claim 15 recites “avoiding serial tests”. The meaning and intent of this phrase is unclear within the claimed method. Is this an attempt to close the claimed method to further steps or to limit the claimed method to being employed without any other tests being performed on the cell type used in the test?

Claim 15 recites “in a time-resolved manner”. It is unclear what this phrase means as it does not appear to be a term of art.

Claims 16, 18–26 use the phrase “characterized in that”. It is uncertain whether this phase is open to further characteristics or is closed to further characteristics. Please use “comprising”, “consisting of”, “wherein”, etc..

Regarding claim 17, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 17, 22, 23, 26 use the terms, especially or preferably. It is unclear if this recitation further limits the claim.

Claim 19 uses the abbreviation “PNAs” without a definition. Use of abbreviations may permit unfavorable interpretations.

Claim 28 provides for the use of a composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections – 35 USC § 101

Claim 28 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper

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process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15–28 are rejected under 35 U.S.C. 102(b) as being anticipated by Schutte *et al.* [U].

The claims are directed to a method of detecting apoptosis induced by a substance comprising incubating the substance concurrently with a PS marker and detecting the binding between the marker and PS.

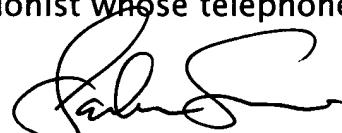
Schutte *et al.* disclose a method of measuring apoptosis induced by a substance (okadaic acid or roscovitine) comprising incubating the cells with the substance for a period of time and then adding annexin V-FITC to the medium and further incubating. It appears that no washing step is performed between the addition of the substance and the addition of annexin V-FITC; thus, the incubation of marker and substance is concurrent. (Page 65, figure legends). PI is also used as a measure of necrosis. Imaging is by confocal scanning laser microscopy or flow cytometry. Cells identified as apoptotic are standardized for the total number of cells (Fig. 3). Parallel cultures (controls) are also analyzed (page 66). The detection step is by flow cytometry or confocal scanning laser microscopy which are the same detection methods in the instant method; therefore, the time taken to perform the same methods may be reasonably assumed to be the same length of time. The Ca++ concentration in DMEM/F12 is about 1mM.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (703) 308-4742. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.



Sandra Saucier
Primary Examiner
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